

building no later than 9 a.m. e.s.t. to allow for enough time to clear security and to check in before the meeting begins. The on-site check-in for visitors will begin at 9:30 a.m. e.s.t. All items brought to the building, whether personal or for the purpose of demonstration or to support a presentation, including items such as laptops, cell phones, and palm pilots, are subject to physical inspection.

Security measures include the following:

- Presentation of government-issued photographic identification to the Federal Protective Service or Guard Service personnel.
- Interior and exterior inspection of vehicles (this includes engine and trunk inspection) at the entrance to the grounds. Parking permits and instructions will be issued after the vehicle inspection.
- Passing through a metal detector and inspection of items brought into the building.

We note that all items brought to CMS, whether personal or for the purpose of demonstration or to support a demonstration, are subject to inspection. We cannot assume responsibility for coordinating the receipt, transfer, transport, storage, setup, safety, or timely arrival of any personal belongings or items used for demonstration or to support a demonstration.

Note: *Individuals who are not registered in advance will not be permitted to enter the building and will be unable to attend the meeting. The public may not enter the building earlier than 45 minutes prior to the convening of the meeting. All visitors must be escorted in areas other than the lower and first floor levels in the Central Building. Seating capacity is limited to the first 250 registrants.*

Authority: Section 503 of Public Law 108–173.

(Catalog of Federal Domestic Assistance Program No. 93.773, Medicare—Hospital Insurance; and Program No. 93.774, Medicare—Supplementary Medical Insurance Program).

Dated: December 7, 2010.

Donald M. Berwick,
Administrator, Centers for Medicare & Medicaid Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2009–D–0008]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995 (PRA).

DATES: Fax written comments on the collection of information by January 14, 2011.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, *Attn:* FDA Desk Officer, *FAX:* 202–395–7285, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910—NEW and title “Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act.” Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Elizabeth Berbakos, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50–400B, Rockville, MD 20850. 301–796–3792. E-mail: *elizabeth.berbakos@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Guidance for Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act

In the **Federal Register** of January 21, 2009 (74 FR 3611), FDA announced the availability of a draft guidance for industry entitled “Draft Guidance for

Industry on Citizen Petitions and Petitions for Stay of Action Subject to Section 505(q) of the Federal Food, Drug, and Cosmetic Act” (FD&C Act). FDA is now in the process of finalizing this guidance. In that **Federal Register** notice, FDA provided the public with 60 days to comment on the proposed collection of information. FDA received no comments pertaining to the information collection in the draft guidance.

Description of Respondents:

Respondents to this collection of information as it is related to citizen petitions are individuals or households, State or local governments, not-for-profit institutions, and businesses or other for-profit institutions or groups. Respondents to this collection of information as it is related to petitions for stay of Agency action are persons who choose to file a petition for an administrative stay of action.

Burden Estimate: Section 505(q)(1)(H) of the FD&C Act requires that citizen petitions and petitions for stay of Agency action that are subject to section 505(q) include a certification to be considered for review by FDA. Section 505(q)(1)(I) of the FD&C Act requires that supplemental information or comments to such citizen petitions and petitions for stay of Agency action include a verification to be accepted for review by FDA. This guidance describes our current thinking on the interpretation of these requirements. The guidance sets forth the criteria the Agency will use in determining if the provisions of section 505(q) apply to a particular citizen petition or petition for stay of agency action. One of the criteria for a citizen petition or petition for stay of Agency action to be subject to section 505(q) of the FD&C Act is that a related ANDA or 505(b)(2) application is pending at the time the citizen petition or petition for stay is submitted. Because petitioners or commenters may not be aware of the existence of a pending ANDA or 505(b)(2) application, the guidance recommends that all petitioners challenging the approvability of a possible ANDA or 505(b)(2) application include the certification required in section 505(q)(1)(H) of the FD&C Act and that petitioners and commenters submitting supplements or comments, respectively, to a citizen petition or petition for stay of action challenging the approvability of a possible ANDA or 505(b)(2) application include the verification required in section 505(q)(1)(I) of the FD&C Act. The guidance also recommends that if a petitioner submits a citizen petition or petition for stay of Agency action that is missing the

required certification but is otherwise within the scope of section 505(q) of the FD&C Act and the petitioner would like FDA to review the citizen petition or petition for stay of Agency action, the petitioner should submit a letter withdrawing the deficient petition and submit a new petition that contains the required certification.

FDA currently has OMB approval for the collection of information entitled, "General Administrative Procedures: Citizen Petitions; Petition for Reconsideration or Stay of Action; Advisory Opinions" (OMB Control Number 0910-0183). This collection of information includes, among other things: (1) The format and procedures by which an interested person may submit to FDA, in accordance with § 10.20 (21 CFR 10.20), a citizen petition requesting the Commissioner of Food and Drugs (Commissioner) to issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action (§ 10.30(b) (21 CFR 10.30(b))); (2) the submission of written comments on a filed citizen petition (§ 10.30(d)); (3) the submission of a supplement or amendment to or a letter to withdraw a filed citizen petition (§ 10.30(g)); (4) the format and procedures by which an interested person may request, in accordance with § 10.20, the Commissioner to stay the effective date of any administrative action (§ 10.35(b) (21 CFR 10.35(b))); and (5) the submission of written comments on a filed petition for administrative stay of

action (§ 10.35(c)). This information collection includes citizen petitions, petitions for administrative stay of action, comments to petitions, supplements to citizen petitions, and letters to withdraw a citizen petition, as described previously in this document, that are subject to section 505(q) of the FD&C Act and described in the guidance.

Under section 505(q) of the FD&C Act and the guidance, the following information would be submitted to FDA but is not currently approved by OMB under the PRA:

1. The certification required under section 505(q)(1)(H) of the FD&C Act for citizen petitions that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application. Although the submission of a certification for citizen petitions is approved under OMB Control Number 0910-0183, the certification would be broadened under section 505(q) of the FD&C Act and the guidance.

2. The certification required under section 505(q)(1)(H) of the FD&C Act for petitions for stay of Agency action that are subject to section 505(q) and/or that are challenging the approvability of a possible ANDA or 505(b)(2) application.

3. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to citizen petitions.

4. The verification required under section 505(q)(1)(I) of the FD&C Act for comments to petitions for stay of Agency action.

5. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to citizen petitions.

6. Supplements to petitions for stay of Agency action.

7. The verification required under section 505(q)(1)(I) of the FD&C Act for supplements to petitions for stay of Agency action.

8. The letter submitted by a petitioner withdrawing a deficient petition for stay of Agency action that is missing the required certification but is otherwise within the scope of section 505(q) of the FD&C Act.

Section 505(q)(1)(B) and (C) of the FD&C Act and the guidance state that if FDA determines that a delay in approval of an ANDA or 505(b)(2) application is necessary based on a petition subject to section 505(q), the applicant may submit to the petition docket clarifications or additional data to allow FDA to review the petition promptly. This information collection is not included in this analysis because it is approved under OMB Control Number 0910-0001 (21 CFR 314.54, 314.94, and 314.102).

Based on FDA's knowledge of citizen petitions and petitions for stay of Agency action subject to section 505(q) of the FD&C Act that have been submitted to FDA, as well as the Agency's familiarity with the time needed to prepare a supplement, a certification, and a verification.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹

	Number of respondents	Annual frequency per response	Total annual responses	Hours per response	Total hours
Certification for citizen petitions (505(q)(1)(H))	19	1.32	25	0.5	12.5
Certification for petitions for stay of Agency action (505(q)(1)(H))	3	1	3	0.5	1.5
Verification for comments to citizen petitions (505(q)(1)(I))	9	1.33	12	0.5	6.0
Verification for comments to petitions for stay of Agency action (505(q)(1)(I))	2	1	2	0.5	1.0
Verification for supplements to citizen petitions (505(q)(1)(I))	7	1.43	10	0.5	5.0
Supplements to petitions for stay of Agency action ..	1	1	1	6.0	6.0
Verification for supplements to petitions for stay of Agency action (505(q)(1)(I))	1	1	1	0.5	0.5
Letter withdrawing a petition for stay of Agency action	1	1	1	0.5	0.5
Total Hours					33

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

